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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,968	05/09/2005	Pallav Arvind Bulsara	PG4715USw	6143

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EXAMINER
AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,968	BULSARA ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-12 and 14-25* is/are pending in the application.

4a) Of the above claim(s) *12 and 14-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' amendment, which was filed on 3 April 2007.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 9-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (EP 0 416 951 A1) in view of Blair, et. al. (WO 0215876 A2), further in view of Roser, et. al. (WO 9603978).

Palmer teaches a dry powder formulation (*see* page 2, lines 39-46; examples 6-11). The disclosed formulation is comprised of:

- the salmeterol of instant claims 1 and 2 (*see* page 2, lines 32 and 48; examples 6-11);
- the fluticasone propionate of instant claim 1 (*see* page 2, lines 33 and 48; examples 6-11);
- the 1-hydroxy-2-naphthoate salt of instant claim 2 (*see* page 3, line 8);
- the lactose excipient of instant claims 1, 9, and 10 (*see* page 3, line 22; examples 6-11); and

- the therapeutic use of instant claim 11 (*see* page 2, line 55 – page 3, line 1; examples 6-11).

Palmer explains that the disclosed formulation is beneficial because of improved efficiency and duration of bronchodilation as well as providing the ease of twice daily administration (*see* page 2, lines 28-31).

While the Palmer reference does not explicitly teach particle size ranges of instant claim 9, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable sizes through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such size is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant size ranges.

The Palmer reference differs from the instant application in that it does not disclose a derivatized carbohydrate of instant claims 1 and 3-8.

Blair, et. al. teach hydrophobically derivatized carbohydrates as carrier particles in dry powder inhalers (*see* page 1, lines 3-4; page 2, lines 4-6). The disclosed derivatized carbohydrates comprise:

- the mono or disaccharide with a substituted hydrophobic moiety via either ester or ether linkages of instant claim 3 (*see* page 3, lines 11-13);
- the trehalose of instant claim 4 (*see* page 3, line 19);
- the trehalose octaacetate of instant claim 5 (*see* page 3, line 19);
- the cellobiose octaacetate of instant claim 6 (*see* page 3, line 17 – incorporated by reference from WO 9603978; page 21, line 24; claim 11);
- the less than 10% derivatized carbohydrate concentration of instant claim 7 (*see* page 3, lines 27-28); and

Blair, et. al. explain that derivatized carbohydrates demonstrate an improved emitted dose uniformity compared to both crystalline trehalose and lactose as well as a high fine particle fraction (*see* page 5, lines 23-26).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a dry powder pharmaceutical composition for inhalation therapy comprising salmeterol and fluticasone propionate, a lactose excipient, and a derivatized carbohydrate, as taught by Palmer, in view of Blair, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because of improved efficiency and duration of bronchodilation as well as providing the ease of twice daily administration, as explained by Plamer, as well as improved emitted dose uniformity and high fine particle fraction, as taught by Blair, et. al.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 10/511,042 ('042). Although the conflicting claims are not identical, they are not patentably distinct from each other because '042 claims a dry powder pharmaceutical composition for inhalation therapy comprising a pharmaceutically active agent, an excipient, and a derivatized carbohydrate in particulate form (claim 3).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed 3 April 2007 have been fully considered but they are not persuasive.

1. Applicants argue that the instant application is distinguished from the prior art because the instant application claims derivatized carbohydrate particles with a size range of 1-20 μm. *See* amendment, page 6, fifth full-paragraph.

A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) *See* MPEP 2144.05.

The Blair reference teaches derivatized carbohydrate particles of 30 μm (*see* page 2, line 16). The instant specification recites derivatized carbohydrate particles of 50 μm. Thus, the instant specification recites derivatized carbohydrate particles which are larger than the prior art. As such, examiner respectfully submits that the derivatized carbohydrate particle size range recited by the instant application is obvious in view of the prior art.

2. Applicants argue that they use derivatized carbohydrate particles for improved stability, while the Blair reference discloses the use of derivatized carbohydrate particles as carrier materials. *See* amendment, page 6, last paragraph.

Examiner respectfully submits that the difference in purpose does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different

purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N SHEIKH
PRIMARY EXAMINER